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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,958	08/13/2001	Masayoshi Nanba	2519US0P	8993

23115 7590 06/02/2003

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
475 HALF DAY ROAD
SUITE 500
LINCOLNSHIRE, IL 60069

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/02/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n N .		Applicant(s)	
	09/673,958		NANBA ET AL.	
	Examiner		Art Unit	
	Brian Whiteman		1635	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 14 March 2003.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-5 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 8/13/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>g</u> .	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other:
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DETAILED ACTION

Non-Final Rejection

The amendment to the specification, and the amendment to claims 1, 3, 4, 8, 10, and 11 in paper no. 13 filed on 3/14/03 is acknowledged and considered.

Claims 1-11 are pending.

Election/Restrictions

Applicant's election of Group I in Paper No. Paper no. 13 filed on 3/14/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In view of the amendment to claims 8-11, the examiner considers the amended claims to be directed to a non-elected invention because the technical feature linking the inventions does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Claims 6-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made without traverse in Paper No. 13 filed on 3/14/03.

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Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The international search report has been considered.

Drawings

New corrected drawings are required in this application because of the objection by the draftsperson. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

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The abstract of the disclosure is objected to because the abstract is more than 25 lines and the terms "mean" and "said". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of the immortalized hepatocyte cell culture FERM BP-6328. While the specification provides enough information for one of skill in the art to produce the immortalized hepatocyte cell culture with same or similar properties as the cell culture FERM BP-6328, reproduction of the identical immortalized hepatocyte cell culture is an unpredictable event.

It does not appear that the immortalized hepatocyte cell culture FERM BP-6328 is both known and readily available or can be reproducibly made or isolated from nature without undue experimentation, and because claim 5 specifically requires the cell culture FERM BP-63428, a suitable deposit of on page 21 of the specification is noted but is considered insufficient assurance that all of the conditions of 37 CFR

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1.801-1.809 have been met. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request of the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of



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each member State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:


A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukaya et al., (IDS, Gekkan Soshiki Baiyou Kougaku, 23: 292-297, 1997). Fukaya describes the insertion of the T-antigen gene from SV40 to obtain an immortalized hepatic cell line (OUMS-26) originating in normal human cells, which sustains p450 activity (pages 294 and 296).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfeifer et al. (PNAS 90:5123-5127, 1993). Pfeifer teaches immortalized human liver cells that express hepatocyte characteristics (abstract). The liver cells expressed CYPIA1/1A2, epoxide hydrolase, NADPH CYP reductase, SOD, catalase, glutathione S-transferase, and glutathione peroxidase (pages 5126-5127).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris et al. (US Patent 5,506,131). Harris teaches an immortalized human hepatocyte cell line, wherein the cells are capable of expression human cytochrome p450 genes, wherein the cytochrome P450 is



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CYP1A1, CYP1A2, CYP1A3 (columns 5, 6, 19, and 20). Immortalized cells preferably retain expression of phase II enzymes, such epoxide hydrolase, catalase, glutathione peroxidase, superoxide dismutase and glutathione S-transferase (column 4, line 34-column 5, line 16).

Double Patenting


The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/009,158. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims from both application embrace an immortalized hepatocyte cell line of human cell origin stably expressing human cytochrome P450.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.



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Conclusion

US Patent 5,660,986 and US Patent 5,665,589 are cited on the PTO-892 because either patent also anticipates claims 1-4. The subject matter in '986 and '589 is essentially the same as US Patent 5,506,131.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

Scott D. Prieb
PRIMARY EXAMINER
SCOTT D. PRIEBE, PH.D.